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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,148	12/02/2004	Alan Michael Sawyer	2004_1542A	9045

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EXAMINER	
SANG, HONG	

ART UNIT	PAPER NUMBER
1643	

NOTIFICATION DATE	DELIVERY MODE
06/22/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/511,148	SAWYER ET AL.	
	Examiner	Art Unit	
	HONG SANG	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-13,16,17 and 20-31* is/are pending in the application.

4a) Of the above claim(s) *17,20-26,29 and 31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-13,16, 27, 28 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

RE: Sawyer et al.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/23/2010 has been entered.

2. Claims 1, 2, 4-13, 16, 17 and 20-31 are pending. Claims 3, 14, 15, 18 and 19 have been cancelled. Claims 16, 17, 20-26, 29 and 31 have been withdrawn from consideration. Claims 1 and 27 have been amended.

3. Upon further consideration, the requirement for restriction between inventions of Groups I and II set forth in office action mailed on 8/11/2006 is withdrawn. Claim 16 is rejoined.

4. Claims 1, 2, 4-13, 16, 27, 28 and 30 are under examination. Due to species election, claims are examined to the extent that the purified candidate antigens are purified proteinaceous substances, and the purified proteinaceous substances are peptides.

Objections Withdrawn

5. The objection to claim 27 for reciting the phrase “a single suspension of antibody-producing cells" is withdrawn in view of applicant’s amendment to the claim.

Rejections Withdrawn

6. The rejection of claims 1, 2, 4-13, 27, 28 and 30 under 35 U.S.C. 103(a) as being unpatentable over Chen (CN 1274085A, Pub. Date: 11/22/2000, see the English translation submitted with IDS on 5/3/2007), in view of Rava et al (US Patent 6,720,149; Date of Patent: 4/13/2004, earliest effective filing date: 6/7/1994), Klessing et al. (US 5,989,846, Date of Patent: 11/23/1999), Poethke et al. (Biol. Chem., 1997, 378: 997-1004), Hu (US 2002/0048823A1, Pub. Date: 4/25/2002, earliest effective filing date: 8/11/2000), and Sanderson et al. (US, 6,821,517B1, Date of Patent 11/23/2004, earliest effective filing date: 10/18/1996) is withdrawn in view of the Declaration of Dr. Thomas Joos submitted under 37 C.F.R. §1.132 and new grounds of rejection.

New Grounds of Objections and Rejections

Claim Objections

7. Claim 16 is objected to for reciting “selecting as said” and “that which”.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 recites the limitation "said step of detecting the monoclonal antibodies…". Claim 12 recites the limitation “said step of detecting and isotyping the monoclonal antibodies…”. There is insufficient antecedent basis for these limitations in the claims. Claim 1 only mentions "screening the supernatant of said immortalized cell lines...".

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 2, 4-13, 16, 27, 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashkenazi et al. (US 6,252,050B1, Date of Patent: 6/26/2001), in view of Snyder et al. (US 2003/0207467A1, Pub. Date: 11/6/2003, earliest effective filing date: 5/4/2000), Scheinberg et al. (J. Immuol. Methods, 1983, 58:285-292), and Frengen (US 5,739,042, Date of Patent: 4/14/1998).

Ashkenazi et al. teach a method for making monoclonal antibodies, comprising (a) immunizing an animal with two or more different antigens (for example from about two to about ten different antigens); (b) fusing a single cell suspension of immune cells

obtained from the immunized animal with myeloma cells in order to generate hybridoma cell lines producing monoclonal antibodies; and (c) screening said monoclonal antibodies to identify one or more monoclonal antibodies that bind to each antigen (see column 2, lines 35-65, column 3, lines 1-42, column 15, lines 1-12 and Example 2), wherein the antigen is a protein, peptide, or carbohydrate (see column 8,lines 30-47) and each antigen is preferably purified to form an essentially homogeneous preparation of the antigen (see column 13, lines 47-61), the animal may be a rodent, a rabbit, or a pig (see column 9, lines 61-67), said screening is subjecting one or more monoclonal antibodies (e.g. purified antibody and/or hybridoma culture supernatant comprising the antibody) to one or more assays such as ELISAs, FACS assays which determine qualitatively and/or quantitatively the ability of an antibody to bind to an antigen of interest (see column 10, lines 38-42). Ashkenazi et al. disclose that after hybridoma cells are identified that produce antibodies of the desired specificity, affinity, and/or activity, single cell clones may be subcloned, and the monoclonal antibodies secreted by the subclones are suitable separated from the culture medium by conventional immunoglobulin purification procedures (see column 17, lines 9-28). Ashkenazi et al. teach that the amount of each antigen administered to the host animal may, for example, range from about 0.01 μg to about 250 μg (see column, 14, last paragraph), and it may be desirable to boost the animal at spaced intervals until the antibody titer increases or plateaus (see column 15, lines 21-26). Ashkenazi et al. disclose that the class/subclass of the antibodies may be determined by antibody capture on antigen-

coated plates and/or antibody capture on anti-IgG antibodies (see column 16, lines 62-65 and Example 5).

Ashkenazi et al. do not teach screening antibodies using a protein chip on which the purified candidate antigens are displayed. Ashkenazi et al. do not teach that for antibody isotyping, each anti-immunoglobulin antibody having different isotype specificity has a different label. However, these deficiencies are made up for in the teachings of Snyder, Scheinberg and Frengen.

Snyder et al. disclose a method of determining the specificity of an antibody preparation comprising the steps of: (a) contacting a positionally addressable array with an antibody preparation, said array comprising a plurality of potential antigens on a solid support, with each different antigen being at a different position on the solid support, wherein the density of different antigens is at least 100 different antigens per cm^2; and (b) detecting positions on the solid support where binding by an antibody in said antibody preparation occurs, wherein the antibody preparation comprises antiserum, a monoclonal antibody, or a polyclonal antibody, wherein the antibody binding is detected by contacting the array with a fluorescently labeled secondary antibody that binds to antibody in said antibody preparation; removing unbound secondary antibody; and detecting bound label on the array (see claims 82-91). Snyder et al. disclose that a protein chip with densely packed wells in which assays can be conducted allows large-scale parallel analysis of the presence, amount and/or functionality of proteins (see paragraphs [0013]), [0014]), [0016] and [0054]).

Scheinberg et al. disclose a method for mass screening of monoclonal antibodies and immunoglobulin isotype using an 8x12 array of beads on stalks (microsticks) designed to fit into a 96 well plate, the method allows the processing of 96 samples at once, aseptically if necessary, and does not require expensive equipment (see page 286, paragraph 2). Scheinberg et al. disclose screening the hybridomas directly against the antigen coated to the sticks (see page 290, last paragraph and Figure 5). Scheinberg et al. disclose that the microstick radioimmunoassay is as sensitive as the currently used microtiter plate radioimmunoassay in screening for monoclonal antibodies in hybridoma supernatant fluid, more important, the assay is much more rapid because the 96 sticks are processed at once (see page 292, Conclusion).

Frengen discloses that if the analyte is an antibody of a defined specificity, different labels, e.g. with different colors of fluorescence may be utilized to quantify different amount of various subclass of the analyte, e.g. isotype classes of the specific antibody (see column 8, lines 1-15).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the method of Ashkenazi to use a protein chip to screen and isotype monoclonal antibody in view of Snyder and Scheinberg. One of ordinary skill in the art would have been motivated to do so because Snyder et al. teach that protein chips allow large-scale parallel analysis of the presence, amount and/or functionality of proteins, and Scheinberg et al. disclose that the microstick radioimmunoassay is as sensitive as the currently used microtiter plate radioimmunoassay in screening for monoclonal antibodies in hybridoma supernatant

fluid, more important, the assay is much more rapid because the 96 sticks are processed at once (see page 292, Conclusion). One of ordinary skill in the art would have had a reasonable expectation of success to modify the method of Ashkenazi to use a protein chip to screen and isotype monoclonal antibody because methods of screening and isotyping monoclonal antibodies using a protein chip were known in the art as shown by Snyder and Scheinberg.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use different labels for labeling different anti-immunoglobulin antibody having different isotype specificity in view of Frengen. One of ordinary skill in the art would have been motivated to do so because Frengen teaches that using different labels allows simultaneous detection of a plurality of analytes at once. One of ordinary skill in the art would have reasonable expectation of success because antibody isotyping using different labels were known in the art as shown by Frengen.

Conclusion

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643